

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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In re Patent Application of:  
J. Michael Ramstack, Ph.D., et al.

**Divisional of Application No.: 10/259,949**

Group Art Unit: N/A

Filed: October 9, 2003

Examiner: Not Yet Assigned

For: PREPARATION OF INJECTABLE  
SUSPENSIONS HAVING IMPROVED  
INJECTABILITY

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**Information Disclosure Statement**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO/SB/08a/b are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith. It is further understood that the Examiner will consider information that

had been cited by or submitted to the U.S. Patent and Trademark Office in a prior application relied on under 35 U.S.C. § 120. 1138 OG 37, 38 (May 19, 1992).

Applicants have checked the appropriate boxes below.

- ☒ 1. This Information Disclosure Statement is being filed within three months of the U.S. filing date OR before the mailing date of a first Office Action on the merits. No statement under 37 C.F.R. § 1.97(e) or fee is required.
- ☐ 2. This Information Disclosure Statement is being filed more than three months after the U.S. filing date AND after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Rejection or Notice of Allowance.
- ☐ a. I hereby state that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(1).
- ☐ b. I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to my knowledge after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(2).
- ☐ c. Attached is our Check No. \_\_\_\_\_ that includes \$180.00 in payment of the fee under 37 C.F.R. § 1.17(p).
- ☐ 3. This Information Disclosure Statement is being filed more than three months after the U.S. filing date and after the mailing date of a Final Rejection or Notice of Allowance, but before payment of the Issue Fee. It is hereby requested that the Information Disclosure Statement be considered. Attached is our Check No.

\_\_\_\_\_ in the amount of \$ \_\_\_\_\_ in payment of the fee under 37 C.F.R. § 1.17(i).

- ☐ a. I hereby state that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(1).
- ☐ b. I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to my knowledge after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(2).
- ☐ 4. Relevance of the non-English language document(s) is discussed in the present specification.
- ☐ 5. The document(s) was/were cited in a corresponding foreign application. An English language version of the foreign search report is attached for the Examiner's information.
- ☐ 6. A concise explanation of the relevance of the non-English language document(s) appears below:
- ☒ 7. The Examiner's attention is directed to co-pending U.S. Patent Application No. 10/259,949, filed September 30, 2002, which is directed to related technical subject matter. The identification of this U.S. Patent Application is not to be construed as a waiver of secrecy as to that application now or upon issuance of the present application as a patent. The Examiner is respectfully requested to consider the cited application and the art cited therein during examination.
- ☒ 8. Copies of the documents were cited by or submitted to the Office in Application Nos. 10/259,949, filed September 30, 2002, and 09/577,875, filed May 25, 2000,

which are relied upon for an earlier filing date under 35 U.S.C. § 120. Thus, copies of these documents are not attached. 37 C.F.R. § 1.98(d).

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO/SB/08a/b, and to indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 50-0740, referencing Docket No. 00166.0073.US02.

Dated: October 9, 2003

Respectfully submitted,

By

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Attorney for Applicant

Substitute for form 1449A/B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	Divisional of 10/259,949
				Filing Date	October 9, 2003
				First Named Inventor	J. Michael Ramstack
				Art Unit	N/A
				Examiner Name	Not Yet Assigned
Sheet	1	of	2	Attorney Docket Number	000166.0073-US02

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	AA	US-3,523,906	08/1970	Vrancken et al.	
	AB	US-3,691,090	09/1972	Kitajima et al.	
	AC	US-3,700,215	10/1972	Hardman et al.	
	AD	US-3,737,337	06/1973	Schnoring et al.	
	AE	US-3,773,919	11/1973	Boswell et al.	
	AF	US-3,891,570	06/1975	Fukushima et al.	
	AG	US-3,960,757	06/1976	Morishita et al.	
	AH	US-4,221,862	09/1980	Naito et al.	
	AI	US-4,384,975	05/1983	Fong	
	AJ	US-4,389,330	06/1983	Tice et al.	
	AK	US-4,530,840	07/1985	Tice et al.	
	AL	US-4,818,517	04/1989	Kwee et al.	
	AM	US-4,940,588	07/1990	Sparks et al.	
	AN	US-5,066,436	11/1991	Komen et al.	
	AO	US-5,385,738	01/1995	Yamahira et al.	
	AP	US-5,407,609	04/1995	Tice et al.	
	AQ	US-5,428,024	06/1995	Chu et al.	
	AR	US-5,478,564	12/1995	Wantier et al.	
	AS	US-5,541,172	07/1996	Labric et al.	
	AT	US-5,650,173-B1	07/1997	Ramstack et al.	
	AU	US-5,612,346	03/1997	Mesens et al.	
	AV	US-5,654,008	08/1997	Herbert et al.	
	AW	US-5,654,010	08/1997	Johnson et al.	
	AX	US-5,656,297	08/1997	Bernstein et al.	
	AY	US-5,656,299	08/1997	Kino et al.	
	AZ	US-5,658,593	08/1997	Orly et al.	
	AA1	US-5,667,808	09/1997	Johnson et al.	
	AB1	US-5,688,801	11/1997	Mesens et al.	
	AC1	US-5,747,058	05/1998	Tipton et al.	
	AD1	US-5,770,231	06/1998	Mesens et al.	
	AE1	US-5,792,477	08/1998	Rickey et al.	
	AF1	US-5,871,778	02/1999	Kino et al.	
	AG1	US-5,916,598	06/1999	Rickey et al.	
	AH1	US-5,942,253	08/1999	Gombotz et al.	
	AI1	US-5,965,168	10/1999	Mesens et al.	
	AJ1	US-6,495,164	12/2002	Ramstack et al.	

FOREIGN PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)			
	BA	-WO 89/03678	05/1989	Lewis et al.	
	BB	WO-WO 90/13361	11/1990	Tice et al.	
	BC	EP-0 486 959-A1	05/1992	Canal et al.	
	BD	WO-WO 94/10982	05/1994	Kino et al.	
	BE	WO-WO 94/25460-A1	11/1994	Janssen Pharmaceutica	
	BF	WO-WO 95/13799	05/1995	Ramstack et al.	

Examiner Signature		Date Considered	
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Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>	
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Sheet	2	of	2	Attorney Docket Number	000166.0073-US02

BG	WO-WO 96/01652-A1	01/1996	Janssen Pharmaceutica N.V.		
BH	WO-WO 96/40049	12/1996	Ekenhoff et al.		
BI	WO-WO 97/41837	11/1997	Rickey et al.		
BJ	WO-WO 97/44039-A1	11/1997	Janssen Pharmaceutica N.V.		
BK	WO-WO 99/12549	03/1999	Illum et al.		
BL	WO-WO 99/25354-A2	05/1999	Pharmaceutic N.V.		
BM	EP-EP 0831773	12/1999	Alkermes Controlled Therapeutics Inc. II		

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS					
Examiner Initials <sup>*</sup>	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			T <sup>2</sup>
	CA	Akers, M.J. et al., "Formulation Design and Development of Parenteral Suspensions," Journal of Parenteral Science and Technology, 41(3):88-95 (May-June 1987).			
	CB	Beck, L.R. et al., Biology of Reproduction, 28:186-195 (February 1983).			
	CC	Bodmeier, R. et al., International Journal of Pharmaceutics, 43:179-186 (1988).			
	CD	Cajavec, Stanislav et al., "The primary chicken vaccination against Newcastle disease with antigenic virus subunits prepared in a water-in-oil-in-water emulsion," Periodicum Biologorum, 99(1):39-44 (1997).			
	CE	Cha, Y and Pitt, C.G., "The Acceleration of Degradation-Controlled Drug Delivery from Polyester Microspheres," Journal of Controlled Release, 8:259-265 (1989).			
	CF	Cha, Y. and Pitt, C.G., "A One-Week Subdermal Delivery System for L-Methadone Based on Biodegradable Microparticles," Journal of Controlled Release, 7:69-78 (1988).			
	CG	"How to Avoid Clogging of Insulin Syringes," Diabetes Forcase, pp. 27-29 (November-December 1976).			
	CH	Jalil, R. et al., Journal of Microencapsulation, 7(3):297-319 (July-September 1990).			
	CI	Li, Wen-I et al., Journal of Controlled Release, 37:199-214 (December 1995).			
	CJ	Maulding, H.V. et al., "Biodegradable Microparticles: Acceleration of Polymeric Excipient Hydrolytic Rate by Incorporation of a Basic Medicament," Journal of Controlled Release, 3:103-117 (March 1986).			
	CK	Pharmaceutical Dosage Forms Disperse Systems, edited by Herbert A. Lieberman, Martin M. Rieger, Gilbert I. Bank, second edition, Chapter 7, "Injectable Emulsions and Suspensions," 1:261-318.			
	CL	Pharmaceutical Dosage forms Disperse Systems, edited by Herbert A. Lieberman, Martin M. Rieger, Gilbert I. Bank, second edition, Chapter 7, "Viscosity-Impairing Agents in Disperse Systems," 2:287-313 (1996).			
	CM	Sah, Hongkee et al., Pharmaceutical Research, 13:360:367 (March 1996).			
	CN	Sato, Toyomi et al., Pharmaceutical Research, 5:21-30 (1988).			
	CO	Zingerman, J.R. et al., "Automatic injector apparatus for studying injectability of parenteral formulations for animal health," International Journal of Pharmaceutics, 36:141-145 (1987).			

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature		Date Considered	
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